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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,665	05/03/2001	Ute Rogner	03495.0203	6991

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,665	ROGNER ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,25,34,40,41,46-48,58 and 62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,25,34,40,41,46-48,58 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6/12/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/31/03 has been entered. Note that claims 17-24 should be indicated as being "canceled".

2. The information disclosure statement filed 7/12/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

3. The rejection of claims 15-19, 22, 24, 34, 40, 46, 48, 56-58 & 60-61 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn due to either the cancellation or amendment of the claims. However, it is still suggested that amending claims 34, 40 & 48 to "an isolated [versus purified] neural/eukaryotic cell would reflect more conventional claim language.

4. The rejection of claims 40 & 41 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling for Deposit information critical or essential to the practice of the invention is withdrawn due to the Declaration by Danielle Berneman.

5. The rejection of claims 16, 25 & 34 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to the amendment of the claims to closed language.

6. The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements is withdrawn due to the cancellation of the claim.

7. The rejections of claim 40 and claims 24 & 40 under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete are withdrawn due to either the cancellation or amendment of the claims, or due to Applicants' arguments.

8. The rejection of claims 19 & 58 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the cancellation or amendment of the claims.

9. The rejection of claims 15, 17, 24-25 & 33 under 35 U.S.C. 102(b) as being anticipated by Adams et al. (clone EST27025; Accession no. AA324132; April, 1997) is withdrawn due to the cancellation or amendment of the claims.

10. The rejection of claims 15-17, 24-25, 33, 41 & 56 under 35 U.S.C. 102(b) as being anticipated by Chen et al. (clone bWXD759; Accession no. AC004074; Jan. 1998) is withdrawn due to the cancellation or amendment of the claims.

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Applicants' arguments filed 10/31/03 have been considered but are not found persuasive.

13. Claims 16, 25, 34, 40-41, 46-48, 58 & 62 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility, for the reasons made of record in Paper No: 15 (mailed 5/2/03), and as follows.

Applicants argue on pages 7-8 of the response that "specific biological activities and specific developmental defects are described in the specification", and then cites general "developmental defects" in mutant mouse embryos, as well as general methods where one skilled in the art is invited to discover the function of Nap1/2. In contrast to Applicants' assertions, as previously made of record, because many genes are reasonably involved in "development of the nervous system and... [have] a putative role... in the control of cell proliferation and differentiation processes", or in the 'control of cancer", and/or may "identify predisposition to developmental defects", no specific utility exists for the instant claimed gene sequences, because no **specific** biological activity nor specific "developmental defect" is described within the specification that is specifically associated with any nucleic acid transcribed by the promoter polynucleotide sequence of SEQ ID NO:4. Likewise, consistent with Applicants' arguments, the claimed polynucleotides have no substantial utility because further experimentation is necessary at the time of filing the instant invention to attribute a "real world" utility to the claimed recombinant polynucleotides. See MPEP 2107.

Accordingly, the instant situation is analogous to that decided by the courts in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. In particular, the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Therefore, because no known "specific" biological activity is described within the instant specification nor specifically associated with any polynucleotide promoter sequence of SEQ ID NO:4 that encodes a polypeptide with a known and assayable biological function, the claimed polynucleotides have no specific nor substantial utility, because further experimentation is also necessary at the time of filing the instant invention to attribute a function and "real world" utility to the claimed polynucleotide molecules.

14. Claims 16, 25, 34, 40-41, 46-48, 58 & 62 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible

asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

15. Claims 40-41, 46-48, 58 & 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 15 (mailed 5/2/03), and as follows.

Applicants argue on pages 9-10 of the response that "written description" of "high stringency" is provided within the specification. In contrast to Applicants' assertions, the rejection is that no other sequences, allelic variants, nor molecules from different species are described within the specification. Not that "high stringency" is described, or not. In other words, one skilled artisan cannot reasonably visualize such polynucleotide sequences with any assayable and functional biological activity (i.e., by SEQ ID NO) based on the limited written description provided in the instant specification, in which the current claims still encompass the genus of such DNA or "gene" sequences, which encompasses unknown 5'-, 3'-flanking, enhancer, additional promoter sequences and other unknown chromosomal sequences, and which would be expected by the skilled artisan to have widely divergent functional properties; thereby, not reasonably meet the written description requirements under 35 U.S.C. 112, first paragraph, because one skilled in the art cannot reasonably visualize or predict what critical nucleotide residues would structurally characterize the genus of polynucleotides currently encompassed by the claims.

Lastly, the specification still fails to provide any written description on what sequences are contained in Accession NOs: I-2463, I-2465 or I-2466. It is noted that the declaration indicated that Accession No. I-2464 is pBPX1. It is further noted that Applicants chose not to amend page 44 of the specification, or argue what constitutes the sequences contained in these deposited plasmids in their response (i.e., as it relates to claim 41).

Applicants are directed toward Examples 6, 7, 9, 11 & 17 of the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999, and MPEP 2163.

16. Should a utility for the instant invention be established, claims 16, 25, 34, 40, 46-48, 58 & 62 are then rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the a promoter polynucleotide sequence consisting of SEQ ID No: 4, does not reasonably provide enablement for any structurally and functionally uncharacterized promoter sequences that merely comprise fragments of SEQ ID NO:4, or merely comprise hybridization products with no known structural nor recited functional characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 15 (mailed 5/2/03), and as follows.

In contrast to Applicants' arguments on page 10 of the response, no distinguishable and assayable functional language is recited in claims 40, 46 & 62 (i.e., as it relates to any hybridizable polynucleotide sequence). In addition, because the metes and bounds of the recitation "**a** promoter function" is unknown or not described within the specification and defines

little, versus a promoter sequence that can transcribe a functional mRNA sequence (which appears to have no proper antecedent basis nor conception within the specification), and because it is unknown what distinguishes the human Nap1L2 promoter of SEQ ID NO:4 from any different promoter sequence, or "promoter function", these claims remain not enabled; consistent with the teachings of LeClerc previously made of record.

17. Claims 46-48 & 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous and contradictory for the polynucleotide of amended claim 46 to "further comprise a heterologous nucleotide sequence... [that is] *operably linked to SEQ ID NO:4*, when base claim 62 is not limited to SEQ ID NO:4. In other words, the "polynucleotide as claimed in claim 62" can only be "operably linked to SEQ ID NO:4", if claim 62 is limited to SEQ ID NO:4, which it is not (i.e., as it relates to the hybridization products, or fragments thereof, recited in claim 62).

18. Claims 40 & 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (clone EST27025; Accession no. AA324132; April, 1997), for the reasons made of record in Paper No: 15 (mailed 5/2/03), and as follows.

In contrast to Applicants' assertions on page 12 of the response, because Adam's clone is 96.9% identical to SEQ ID NO:4, and therefore, would inherently hybridize to SEQ ID NO:4 under high stringency conditions, the limitations of claims 40 & 62 are anticipated.

19. Claims 40, 46-47 & 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (clone bWXD759; Accession no. AC004074; Jan. 1998), for the reasons made of record in Paper No: 15 (mailed 5/2/03), and as follows.

Applicants argue on pages 12-13 of the response that they have amended the claims to "consisting of", and therefore, obviate the instant rejection. In contrast to Applicants' assertions, claims 40 & 46-47 recite the open claim language of "comprising... a gene sequence", in which the natural heterologous Nap1L2 nucleotide sequence that is linked to the SEQ ID NO:4 promoter meets the broad limitations of "further *comprises* a heterologous nucleotide sequence coding for a heterologous polypeptide operably linked to SEQ ID NO:4". Likewise, Chen's clone would inherently hybridize under high stringency with SEQ ID NO:4, since the complementary strand to SEQ ID NO:4 is contained in Chen's clone (i.e., as it relates to new claim 62). Thus, Applicants' arguments are moot, as it relates to these claims.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
January 20, 2004

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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